FEB 15 2005

K 050218

WaveLight®

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:	WaveLight Laser Technologie, AG Am Wolfsmantel 5 91058 Erlangen Germany
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Summary Preparation Date:	December 16, 2004

2. Names

Device Name:	SINON
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. Predicate Devices

This submission refers to the SINON device registered under 510(k) number K040433. Therefore the SINON described here is substantially equivalent to the SINON registered under 510(k) number K040433.
The SINON laser system is furthermore substantially equivalent to the Aesculap-Meditec RubyStar Laser System with Normal and Q-Switch Mode (K991285), the Spectrum Medical Technologies RD-1200 (K910422), the MLT Laser Technologies Inc. MLT R694 (K9909002), the Mehl/Biophile Inc. Chromos 694 (K971814) and WaveLights SINON device (K040384).

4. Device Description

The SINON is a 694 nm Ruby laser system which can be operated in two different modes. The quality-switch or Q-switch or QS Operating Mode is characterized by extremely short pulse widths (ns = 10^{-9}s) and high peak power (MW = 10^{6} W). The QS Operating Mode in the SINON is used for the removal of tattoos and treatment of pigmented lesions. The second mode is the Free-Running Operating Mode which is used for the removal of hair.

5. Indications for Use

The SINON is indicated:

1. In the Q-Switch Mode, for the cutting, vaporization, or ablation of soft tissue. This includes the removal of tattoos and treatment of benign pigmented lesions.
2. In the Free-Running Mode, for the removal of unwanted hair in patients with Fitzpatrick skin types of I and II.

6. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2005

Wavelight Laser Technologie AG
c/o Mr. Morten S. Christensen
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K050218
Trade/Device Name: SINON
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 25, 2005
Received: January 31, 2005

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

WaveLight®

510 (k) Indication for Use

Indications for Use

510(k) Number (if known): K050218
Device Name: SINON

Indications for Use:

1. In the Q-Switch Mode, for the cutting, vaporization, or ablation of soft tissue. This includes the removal of tattoos and treatment of benign pigmented lesions.
2. In the Free-Running Mode, for the removal of unwanted hair in patients with Fitzpatrick skin types of I and II.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050218